SECTION 103

The Examiner has objected to claims 1-2,4-5,and 9, pursuant to Section 103, based upon the combination of Kim (6,270,524) and Davillia (2002/0143386).

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

1. The combination cited by the Examiner, does not teach or suggest all of the claimed limitations of applicant's claimed device.

In claim 1, Applicant claims a flexible, curved anchoring element **(22)** ***which is integrally connected with at least two terminal wall elements*** **(14, 15, 14', 15')** and bridges at least one elastic wall element (14, 15),

In claim 2, it is noted that a "V" shape is preferred for the flexible, curved, anchoring element.

The Examiner has noted that Kim neither teaches or suggests such a component. The Examiner relies on Davillia for the missing elments, indicating that it teaches a curved anchoring element, with a radiopaque tip, which flares outwardly, and bridges at least one wall element, or two wall elements, and, is "V-shaped.

The Examiner may has misread Davila and also missed the element of Applicant's claimed invention as having the V-shaped, curved anchoring elements which are integrally connected with at least two terminal wall elements (14,15,).

The cited reference of Davila, lacks any integral connection and does not connect the anchoring element integrally at the intersections of all elements. In fact, Davila teaches away from this concept entirely. Neither does Davila anywhere, show a V-shaped anchoring element

with the two ends of the "V" connecting integrally with the terminal wall elements 14,15.

Lacking the claimed V-shaped anchoring element which is integrally connected with terminal wall elements 14 and 15, the combination suggested by the Examiner is respectfully traversed.

2. Even if there were not lacking elements in Davila, there is no suggestion or motivation to modify the reference or to combine reference teachings.

Davila as noted, lacks an integral connection of Applicant's claimed anchoring element to wall elements 14 and 15. Instead, Davila teaches the employment of angled bridges 116 to connect the zig-zag or W-shaped anchors and thereby specifically teaches away from Applicant's v-shape construction and integral connection. Davila teaches this offset bridge engagement for very specific functional reasons rather than just a simple engineering or manufacturing choice.

To this end, in Davila, the it is stated that:

(Column 6, line 61) Stent 100 further includes a plurality of bridges 116 which connect adjacent hoops 108 and which can best be described in detail by referring to FIG. 5. Each bridge 116 has two ends 118 and 120. The bridges 116 have one end attached to one strut and/or loop, and another end attached to a strut and/or loop on an adjacent hoop. The bridges 116 connect adjacent struts together at bridge to loop connection points 122 and 124. For example, bridge end 118 is connected to loop 114(a) at bridge to loop connection point 122, and bridge end 120 is connected to loop 114(b) at bridge to loop connection point 124. Each bridge to loop connection point has a center 126. The bridge to loop connection points are separated angularly with respect to the longitudinal axis. That is, the connection points are not immediately opposite each other. Essentially, one could not draw a straight line between the connection points, wherein such line would be parallel to the longitudinal axis of the stent.

(Column 7, line 10) The above described geometry helps to better distribute strain throughout the stent, prevents metal to metal contact when the stent is bent, and minimizes the opening size between the struts, loops and bridges. **The number of and nature of the design of**

the *struts, loops and bridges* are important factors when determining the working properties and fatigue life properties of the stent. It was previously thought that in order to improve the rigidity of the stent, that struts should be large, and therefore there should be fewer struts per hoop. However, it has now been discovered that stents having smaller struts and more struts per hoop actually improve the construction of the stent and provide greater rigidity.

(Column 7, line 30) "As seen from a comparison of FIGS. 2 and 3, the geometry of the stent 100 changes quite significantly as the stent 100 is deployed from its un-expanded state to its expanded state. As a stent undergoes diametric change, the strut angle and strain levels in the loops and bridges are affected. Preferably, all of the stent features will strain in a predictable manor so that the stent is reliable and uniform in strength. In addition, ***it is preferable to minimize the maximum strain experienced by struts loops and bridges***, since Nitinol properties are more generally limited by strain rather than by stress.

Column 7, line 51) In trying to ***minimize the maximum strain*** experienced by features of the stent, the present invention utilizes structural geometries which distribute strain to areas of the stent which are less susceptible to failure than others. For example, one of the most vulnerable areas of the stent is the inside radius of the connecting loops. The connecting loops undergo the most deformation of all the stent features. The inside radius of the loop would normally be the area with the highest level of strain on the stent. This area is also critical in that it is usually the smallest radius on the stent. Stress concentrations are generally controlled or minimized by maintaining the largest radii possible. ***Similarly, we want to minimize local strain concentrations on the bridge and bridge connection points***. One way to accomplish this is to utilize the largest possible radii while maintaining feature widths which are consistent with applied forces. Another consideration is to minimize the maximum open area of the stent. Efficient utilization of the original tube from which the stent is cut increases stent strength and its ability to trap embolic material.

(Column 8, line 5) Many of these design objectives have been accomplished by an exemplary embodiment of the present invention, illustrated in FIGS. 1, 2 and 5. As seen from these figures, the most compact designs which maintain the largest radii at **the loop to bridge connections are**

non-symmetric with respect to the centerline of the strut connecting loop. That is, loop to bridge connection point centers 126 are offset from the center 114 of the loops 112 to which they are attached. **This feature is particularly advantageous for stents having large expansion ratios, which in turn requires them to have extreme bending requirements where large elastic strains are required.** Nitinol can withstand extremely large amounts of elastic strain deformation, so the above features are well suited to stents made from this alloy. This feature allows for maximum utilization of Ni--Ti or other material properties to enhance radial strength, to improve stent strength uniformity, to improve fatigue life by minimizing local strain levels, to allow for smaller open areas which enhance entrapment of embolic material, and to improve stent apposition in irregular vessel wall shapes and curves."

There is no motivation for taking a non-symmetrical, bridge-engaged, non-V-shaped, expansion anchoring component of Davila which is offset by the bridges to resists stress and strain, and change the shape to a V, and eliminate the bridge, and then engage the ends of that V-shaped anchor to that they integrally engage with the wall elements 14,15.

There is no such motivation or teaching since Davila, is teaching for very specific performance reasons of reliving stress and strain on the Davila device, of always using loop to bridge conceptions only, and always using this bridged connection to offset the connection points of the loops, by angling the bridges away from their connection to the terminal wall elements on one end, to their connection to the loops on the other, to achieve this required and desired non-symmetrical engagement of the loop ends.

Further, nowhere in Davila is a V-shaped loop or anchor element employed. Instead, as shown in Figure 3, the anchor elements are zig-zagged or double W in shape in its engagement to the bridges 116.

Thus, Davila, for operative and performance reasons, teaches away from the applicant's claimed flexible, curved anchoring element (22) which is *integrally connected,* with at least two terminal wall elements (14, 15, 14', 15') and bridges at least one elastic wall element, which as clearly taught by Applicant at paragraph 28 of the Applicant's specification, where it clearly states that the tubular stent progresses along an axis 26 and is expanded outward at its ends 20,

20'. The end 20 of the stent shown in FIG. 2, enlarged in FIG. 3 for purposes of improved illustration, shows the structure of the wall segments 11, which are constructed of V-shaped wall elements 14, 15, the V-shaped elements being connected to one another at their tips, thereby forming a zigzag line running circumferentially around the stent longitudinal axis 26. The individual wall elements 14, 15 are formed by elastic elements 14 and 15 connected to one another at their frame tip. In the region of the stent end, the successive, annular wall segments 11 are connected to one another at each of their wall elements 14, 15 by means of connecting elements 12, resulting in a rhombic grid network.

At the end of this grid network structure, the inventive anchoring elements 22 are arranged in such a way that they are *integrally connected with the distal tip of the wall elements 14 and 15.*

As such, the combination suggested by the Examiner is lacking elements of Applicant's claimed invention, and even if it had those elements, there is no motivation for taking a non-symmetrical, bridge-engaged, non-V-shaped, expansion anchoring component of Davila which is offset by the bridges for engineering and specific performance reasons, and eliminate the bridge, and change the shape of the expansion element to a V, and then engage the ends of that V-shaped anchor to that they integrally engage with the wall elements 14,15.

The objection to Applicant's claimed device is thus respectfully traversed as lacking elements of the claimed device, and providing no suggestion or motivation for changing the structure and operation of the cited device of Davillia to make the combination.

The combination with Kim, Davila, and Fischell is also, lacking elements of the claimed invention, and even if not, lacking any motivation to change the structure of Davila and rendering it inoperable for its stated principles to combine it with Kim, is respectfully traversed.

Final Remarks

As noted in the earlier response to the first office action, Applicant's device claims elements providing function, which are neither taught nor suggested in the cited prior art. Applicant as noted in the specification considers the improvement to be substantial and provide great benefits to the patient in whom such a stent is implanted providing both flexibility as well as a solid mount for the device in the curved and flexible environment of a blood vessel.

The art is crowded and as noted, applicant still believes the improvement provided to be significant. However, even if the Examiner does not consider Applicant's claimed device a great advance in the art of vascular stents, it has been established that one should not be deprived of patent protection where it can be shown that any genuine improvement has been made, on comparison with other inventions in the art - even if the improvement lacks the appearance of a great advance in the art.

> In re Lange, 128 USPQ 365, the CCPA on page 367 states that:
> "We think that the present application is a distinct improvement of Jezalik and represents an advance in the art not obvious, having patentable novelty. The art is a crowded and comparatively simple on and in such an art, great advances are not to be expected. *However patentability will not be denied to an invention which accomplishes a small, but nevertheless genuine improvement not though of by others.*."

Further, the CCPA in the recent case of re Meng and Driessen, 181 USPQ 94, on page 97, reiterated the principal that even though the invention seems a simple advance over prior art, *after the fact*, simplicity, argues *for*, rather than against patentability.

Considering that Applicant's device has combined elements not taught or suggested in the prior art, and that the device employed curved and flexible blood vessels of a patient offer an improvement in the art, and considering that both major and minor improvements in the art argue for patentability, the claims of the patent should now be allowable.

Should the Examiner have any further questions or concerns the Examiner wishes to address, or should the Examiner have suggestions as to language that might more clearly define the invention, the Applicant's attorney would be most receptive to such by telephone.

Respectfully submitted,

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